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10/072,900	02/12/2002	Isabelle Arnould-Reguigne	03806.0537	3572

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EXAMINER	
EMCH, GREGORY S	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 12/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/072,900	ARNOULD-REGUIGNE ET AL.	
	Examiner	Art Unit	
	Gregory S. Emch	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 May 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-9,12,13,16-25,41-43,47 and 51-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-9,12,13,16-25,41-43,47 and 51-63* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

Claims 6, 10, 11, 14, 15, 26-40, 44-46, and 48-50 were canceled and claims 1-5, 7, 8, 13, 16, 18, 41-43, and 51-63 were amended in the communication dated May 12, 2005. Currently, claims 1-5, 7-9, 12, 13, 16-25, 41-43, 47, and 51-63 are pending and under consideration.

Response to Amendment and Arguments

The objection to the specification regarding sequences not found in the sequence listing is withdrawn in view of Applicant's amendment dated August 16, 2004. Additionally, the CRF is now in sequence compliance.

The rejection of claim 6 as being a substantial duplicate of claim 1 is rendered moot by cancellation of claim 6 and is thus withdrawn.

The new matter rejection of claims 2, 5, 7, 9, 13, 16, and 17 under 35 U.S.C. 112, first paragraph is withdrawn in view of Applicant's amendments to the claims in the Response filed May 12, 2005.

The rejections of claims 6, 10, 11, 14, 15, 26-40, 44-46, and 48-50 under 35 U.S.C.112, first paragraph and 35 U.S.C. 101 are rendered moot by cancellation of said claims and are thus withdrawn.

The rejections of claims 1-5, 7-9, 12, 13, 16-21, 41-43, 47, and 51-63 under 35 U.S.C. 112, second paragraph are withdrawn in view of Applicant's amendments to the claims in the Response filed May 12, 2005. The rejections of claims 6, 31, 44-46, and

48-50 under 35 U.S.C. 112, second paragraph is rendered moot by cancellation of said claims and is thus withdrawn.

The rejection of claims 2 and 5 under 35 U.S.C. 102(b) as being anticipated by Ansorge et al. is withdrawn in view of Applicant's amendments to the claims in the Response filed May 12, 2005. The rejection of claims 44, 45, 48, and 49 under 35 U.S.C. 102(b) is rendered moot by cancellation of said claims and is thus withdrawn.

New and remaining issues are set forth below.

Claim Rejections - 35 USC § 101, 112, first paragraph

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The rejections of claims 1-5, 7-9, 12, 13, 16-25, 41-43, 47, and 51-63 under 35 U.S.C.112, first paragraph and 35 U.S.C. 101 are maintained for the reasons of record in the office actions dated February 24, 2004 and August 10, 2004.

At p. 7 of the communication dated May 12, 2005, Applicant asserts, "the Lefevre et al. reference of record affirms the teachings of the instant Application," i.e., that the ABCA12 gene is correlated with lamellar ichthyosis and that the gene ABCA12 is expressed in skin. Applicant also asserts, " as is known in the art, a suitable place to

look for functional mutations in the ATP binding portion of the molecule" and "lamellar ichthyosis is an autosomal recessive disorder...with two defective alleles, an artisan would well recognize that it is likely introduction of a normal, expressed allele is a suitable course of gene therapy." Further, on p.8 of said communication, Applicant presents uses of the instant nucleic acids, e.g., production of an ABCA12 protein, assays to detect ABCA12 genomic DNA, mRNA, cDNA and the like, for detecting a mutant or polymorphism, in various assay methods, and obtaining antibodies from the ABCA12 protein, said antibodies can then be used for therapeutic or diagnostic purposes. Hence, Applicant asserts, "Clearly, in the instant application, and hence the claims, provide a number of specific, substantial and credible uses of the nucleic acids of interest.

Applicant's argument has been fully considered and is not found persuasive. As stated in the previous office action dated November 10, 2004, even though ABCA12 is associated with lamellar ichthyosis, Applicants have not taught that administering ABCA12 would be useful in the treatment of the disease. One skilled in the art would not know whether administering ABCA12 would be beneficial or whether inhibiting the activity of ABCA12 would be beneficial. Further research would be required to determine if and how ABCA12 would be useful in the treatment of such a disorder. Even though Lefevre et al. confirm that ABCA12 is associated with lamellar ichthyosis, the specification neither teaches nor suggests the missense mutations as taught by Lefevre et al. Instead, the specification is completely silent as to using ABCA12 to diagnose

lamellar ichthyosis. Teaching that ABCA12 is associated with a disease is not the same as saying that it causes a disease and can be used to diagnose lamellar ichthyosis.

Claims 1-5, 7-9, 12, 13, 16-25, 41-43, 47, and 51-63 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The rejection of claims 2-5, 41-43, 47 and 51 under 35 U.S.C. 112, first paragraph, for lack of enablement, is maintained for reasons of record in the office actions dated February 24, 2004 and November 10, 2004.

On pp.8-9 of the Response filed May 12, 2005, Applicant asserts that the specification teaches methods for producing ABCA12 derivatives and that methods for producing ABCA12 derivatives and methods for identifying the characteristics of ABCA genes and their encoded gene products are well known in the art.

Applicant's argument has been fully considered and is not found persuasive. As stated in the previous office action dated November 10, 2004, the claims have no functional limitations, and such nucleic acid sequences could encode polypeptides that vary greatly from that of ABCA12. Further, the specification does not teach the skilled artisan how to make derivatives of ABCA12 that have the same function as ABCA12. Although, claims 3 and 4 recite a functional limitation, the claims are overly broad in the

recitation of "80 or 85% identity" since insufficient guidance is provided as to which of the myriad of nucleic acid species encompassed by the claim will retain the characteristics of encoding polypeptides that posses the biological activity of any one of the native ABCA12 polypeptides.

The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. The claims, and the predictability of which nucleic acids can be substituted is extremely complex and outside the realm of routine experimentation, because accurate predictions of a nucleic acid molecule's structure from mere sequence data are limited. Since detailed information regarding the structural requirements of any nucleic acid molecule are lacking, it is unpredictable as to which variations, if any, meet the limitations of the claims. Applicant is required to enable one of skill in the art to make and use the claimed invention and it would require undue experimentation for one of skill in the art to make and use the claimed products.

The rejection of claims 2-5, 41-43, 47 and 51 under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement, is maintained for reasons of record in the office actions dated February 24, 2004 and November 10, 2004.

On p.9 of the Response filed May 15, 2005, Applicant argues "an artisan would recognize on reading the instant application, based on the state of the art, that modifications can be made to a nucleic acid as claimed without departing from the spirit

and scope of the invention," and that the instant application discloses uses of the instant nucleic acids.

Applicant's argument has been fully considered and is not found persuasive. As stated in the previous office actions, the claims do not have any functional limitations. Although, claims 3 and 4 recite a functional limitation, the claims are overly broad in the recitation of percent identity since insufficient guidance is provided as to which of the myriad nucleic acid species encompassed by the claim will retain the characteristics of encoding polypeptides that posses the biological activity of any one of the native ABCA12 polypeptides. Furthermore, the specification does not provide a patentable utility or function for ABCA12. The claimed nucleic acid sequences may have functions and structures that differ greatly from that of ABCA12; therefore, one of skill in the art would not be able to predictably identify the encompassed molecules as being the same as those instantly claimed.

Claims 2, 5, 7, 9, 13, 16, 17, 47, and 51-63 are newly rejected under 35 U.S.C. 1 12, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 2, 5, 7, 9, 13, 16, 17, 47, and 51-63 encompass nucleic acid sequences comprising at least 1000, 50 or fewer, 40 or fewer, 35 or fewer, 25 or fewer, or 20 or

fewer consecutive nucleotides, or at least 1000 nucleotides (consecutive or non-consecutive) of any one of SEQ ID NOS: 1-4 or nucleic acid sequences at least 1000 nucleotides in length that hybridize to any one of SEQ ID NOS: 1-4. It is noted that at p. 55 in the specification nucleotide primers of a specific length are taught. However, nowhere in the specification is there any mention requiring sequences to be at least 1000, 50 or fewer, 40 or fewer, 35 or fewer, 25 or fewer, or 20 or fewer consecutive nucleotides, or at least 1000 nucleotides in length or requiring homologous sequences to comprise at least 1000 consecutive nucleotides of any one of SEQ ID NOS: 1-4. There is no written support for the claimed ranges of nucleic acid sequences. Such ranges of nucleic acid sequences are considered to be new matter.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is drawn a kit for detecting the nucleic acid according to claim 1, wherein the kit comprises a) a nucleotide probe selected from the group consisting of 1) a nucleotide probe comprising 50 or fewer consecutive nucleotides of a nucleotide sequence of any one of SEQ ID NOs: 1-4, or a full length complement thereof 2) a nucleotide primer as in claim 7 3) a nucleotide primer as in claim 8; and 4) a nucleotide

probe comprising a nucleotide sequence of any one of SEQ ID NOs: 7-38, or a complementary nucleotide sequence thereof, and optionally, b) reagents necessary for a hybridization reaction. The scope of 1) and 2) is identical as is the scope of 3) and 4), therefore, the metes and bounds of the claim cannot be determined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 7, 16, 52, 53, 60, and 61 under 35 U.S.C. 102(b) as being anticipated by Ansorge et al., GeneBank Accession No. AL080207, is maintained for reasons of record in the office action dated November 10, 2004 and as set forth *infra*. Additionally, claims 13, 54-59, 62, and 63 are newly rejected under 35 U.S.C. 102(b) as being anticipated by Ansorge et al.

The claims are drawn to probes or primers as well as kits comprising probes or primers comprising 50 or fewer, 40 or fewer, 35 or fewer, 25 or fewer, or 20 or fewer consecutive nucleotides of nucleic acid sequences of SEQ ID NOs: 1-4.

The claims recite the open language "comprising," meaning that the molecules are not just limited to the nucleotides instantly claimed. Therefore, as stated in the previous office action, Ansorge et al. teach AL080207, which is 100% identical to SEQ ID NO: 4 at 617 residues, thus meeting the limitations of claims 7, 13, 16, and 52-63.

Also, as stated previously, the "kit" limitation of claims 13, 16, and 56-63 is merely an intended use.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1649.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached on Monday through Friday from 8:30AM to 5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Gregory S. Emch, Ph. D.
Patent Examiner
Art Unit 1649
December 13, 2005

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER